BTRIS

The NIH
Biomedical Translational Research Information System

BTRIS / ClinicalTrials.gov

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ClinicalTrials.gov Requires:

- REGISTRATION Data, submitted by OPS & DCRI
- RESULTS Data, can be done through BTRIS
  - Arm Attribution / Participant Flow
  - Baseline Characteristics
  - Adverse Events
  - Outcome Measures
  - Limitations
  - Agreements

BIOMEDICAL TRANSLATIONAL RESEARCH INFORMATION SYSTEM

National Institutes of Health

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Applications

- Identified Reports
- Limited Data Set Reports
- Subject Attribution
- BTRIS ClinicalTrials.gov

Links

- OHSRP
  Human Subjects Research
- POS
  Protocol Query System
- LID
  Lab for Informatics Dev.
- BTRIS SIG
  Special Interest Group

Get Adobe Reader

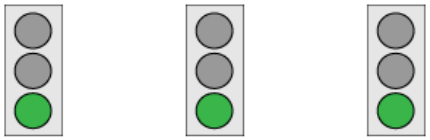
Genomics Data

Now Available as Provided by PI

The Biomedical Translational Research Information System (BTRIS) is a resource available to the NIH intramural community that brings together clinical research data from the Clinical Center (CRIS) and other NIH Institutes and Centers research systems. BTRIS is designed to help clinical researchers retrieve data related to active clinical trials, run limited data set queries for hypothesis testing, attribute to subjects to protocols and assist with mandatory reporting to ClinicalTrials.gov

BTRIS Code of Conduct and Disclaimer

System Status Dashboard (10/31/14)



User Status | Extractors Status | System Status

- **User Status - Identified and Limited Data Set Reports**: Green - Data loaded, report performance good; Yellow - Some data not loaded, reports running slowly;

Publications

Publications Powered by BTRIS Reports

- Publications as of October 2014

Publications About BTRIS

Training

- Publications as of October 2014

Tuesday, November 4, 2-3 PM NIH Library at the Clinical Center BTRIS Basics for Clinical Researchers - Retrieving and Reporting Data for Active Protocols: Register

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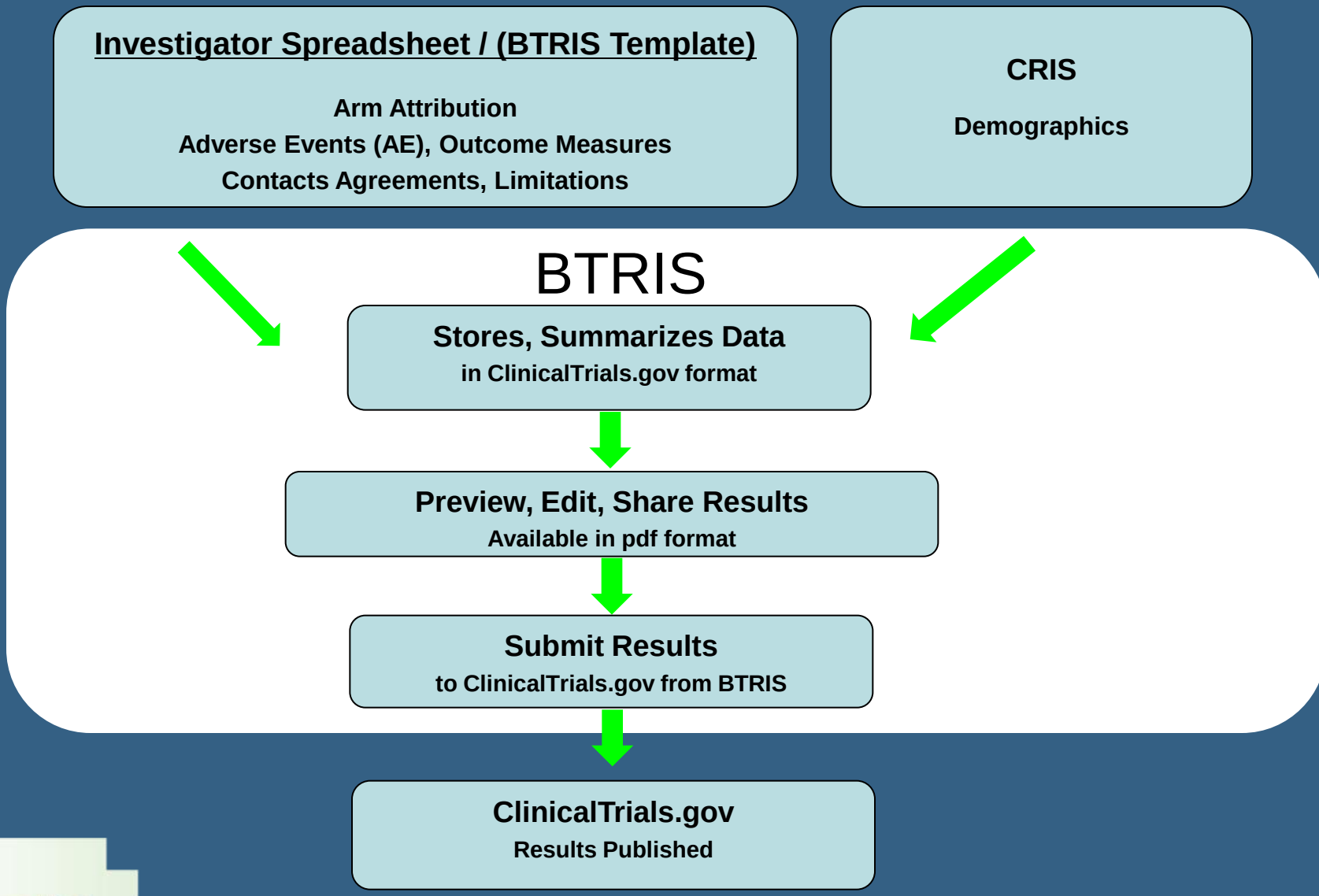
Submitting Results Data to ClinicalTrails.gov via BTRIS

- BTRIS Preferences: allows investigators to…
  …*attribute* subjects to protocols

- ClinicalTrials.gov Submission: allows investigators to…
  …*submit* subject level data to BTRIS
  …*submit* summary data to *ClinicalTrials.gov*

Data Flow from BTRIS to ClinicalTrials.gov



Benefits to BTRIS Users include:

a. Reusing data already existing in BTRIS e.g. demographics

b. Aggregating data in the *ClinicalTrials.gov* defined format from the raw data the user provides

c. Simple, easy to fill spreadsheet provided to populate results data

d. Providing a mapping tool for standardizing (MedDRA) adverse events

e. BTRIS experience submitting results for NHLBI, NIAAA, NIAID, NICHD , NIAMS and NIMH studies

f. Providing a simpler web based user interface focusing on required fields

h. Having an interface to directly submit results to *ClinicalTrials.gov*

i. Providing expertise in *ClinicalTrials.gov* rules/workflows for submission

j. BTRIS closely works with NLM and Institute QA contacts for data submission

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Investigator Spreadsheet (BTRIS Template)

SUBJECT ARM ASSIGNMENT – enter the arm for each subject

	A	B	C	D	E	F
1	**Protocol#**	**MRN**	**Arm/Group Title**	**Started (Y/N)**	**Completed (Y/N)**	
2	08-AA-0058	1234567	Acamprosate	Y	Y	
3	08-AA-0058	1234568	Acamprosate	Y	Y	
4	08-AA-0058	1234569	Acamprosate	Y	Y	
5	08-AA-0058	1234570	Placebo	Y	Y	
6	08-AA-0058	1234571	Placebo	Y	Y	
7						

	A	B	C	D	E	F	G
	Protocol#	**Name**	**Organization Name**	**Phone**	**Phone Ext**	**Email**	**Are all PIs Employees of Sponsor?**
	08-AA-0058	Markus Heilig	NIAAA	301-222-2222		mheilig@mail.nih.gov	No

Investigator Spreadsheet (BTRIS Template)

OUTCOME MEASURES – enter protocol outcome measures and associated data

Protocol#	Outcome Measure Type	Outcome Measure Title	Outcome Measure Description	Outcome Measure Time Frame	Safety Issue	Arm/Group
08-AA-0058	Primary	Alcohol Craving Rating in Response to Saline Infusion	Alcohol craving was measured using the Penn Alcohol Craving Scale (PACS). It is a 5-item self-administered instrument that measures frequency, intensity, and duration of thoughts about drinking, along with ability to resist drinking.	180 minutes after the start of the infusion	No	Acamprosate

Investigator Spreadsheet (BTRIS Template)

ADVERSE EVENTS BY SUBJECT– enter adverse events and associated data for each subject

	A	B	C	D	E	F	G	H	I	J
1	Protocol#	MRN	Frequency Threshold	Adverse Event (From Protocol Records)	Adverse Event (CTCAE/MedDRA Standard)	Arm/Group Title	# At Risk/Group	Serious (Y/N)	Organ System	Onset Date
2	08-AA-0058	1234567	5	High Temperature	Fever	Acamprosate	34	N	General disorders and administration site conditions	
3	08-AA-0058	1234568	5	Pain in the abdomen	Abdominal pain	Acamprosate	34	N	Gastrointestinal disorders	
4	08-AA-0058	1234565	5	Anxiety	Neutrophil count decreased	Acamprosate	35	N	Investigations	
5										
6										
7										
8										
9										
10										

Abdominal distension
Abdominal infection
Abdominal pain
Abdominal soft tissue necrosis
Abducens nerve disorder
Accessory nerve disorder
Acidosis
Acoustic nerve disorder NOS

	A	B	C	D	E	F	G	H	I	J
1	Protocol#	MRN	Frequency Threshold	Adverse Event (From Protocol Records)	Adverse Event (CTCAE/MedDRA Standard)	Arm/Group Title	# At Risk/Group	Serious (Y/N)	Organ System	Onset Date
2	08-AA-0058	1234567	5	High Temperature	Fever	Acamprosate	34	N	General disorders and administration site conditions	
3	08-AA-0058	1234568	5	Pain in the abdomen	Abdominal pain	Acamprosate	34	N	Gastrointestinal disorders	
4	08-AA-0058	1234565	5	Anxiety	Neutrophil count decreased	Acamprosate	35	N	Investigations	
5					Acidosis				Metabolism and nutrition disorders	

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Investigator Spreadsheet (BTRIS Template)

CONTACT AGREEMENT LIMITATIONS – enter a single row of data for populating several sections of the ClinicalTrials.gov website

	A	B	C	D	E	F	G
	Protocol#	**Name**	**Organization Name**	**Phone**	**Phone Ext**	**Email**	**Are all PIs Employees of Sponsor?**
	08-AA-0058	Markus Heilig	NIAAA	301-222-2222		mheilig@mail.nih.gov	No

BTRIS Tabulation of Baseline Characteristics

Protocol: 98-CH-0111

[+] Expand All [-] Hide All

[+] Arm / Group

[+] Adverse Event Threshold

[+] Subject Data

[+] Point of Contact

[+] Certain Agreements

[+] Participant Flow

[-] Baseline Characteristics

Baseline Measure	Orlistat	Placebo	Total
Number of Participants	100	100	200
Age (Unit: participants)			
<=18 years	100	100	200
>18 and <65 years	0	0	0
>=65 years	0	0	0
Gender (Unit: participants)			
Male	35	34	69
Female	65	66	131
Race (Unit: participants)			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	61	58	119
White	38	42	80
More than one race	1	0	1
Unknown or Not Reported Race	0	0	0
Ethnicity (Unit: participants)			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	98	100	198
Unknown or Not Reported Ethnicity	2	0	2

[+] Outcome Measures

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BTRIS Tabulation of Adverse Events

[+] Baseline Characteristics

[+] Outcome Measures

[-] Limitations and Caveats

Overall Limitations and Caveats (max: 250 characters):

This is a

Save Changes

[-] Adverse Events

SERIOUS ADVERSE EVENTS	Orlistat	Placebo
Total, Serious AEs (# participants /# at risk)	0/100	2/100
Endocrine disorders Hypoglycemia - pharmacy error in preparing insulin		1/100(1%)
Gastrointestinal disorders Left lower quadrant pain and vomiting - admitted overnight		1/100(1%)

OTHER ADVERSE EVENTS	Orlistat	Placebo	Frequency Threshold
Total, Non-Serious AEs (# participants /# at risk)	95/100	94/100	3%
Cardiac disorders HEART RACING - 2X	1/100(1%)		3%
increased blood pressure	1/100(1%)		3%
Ear and labyrinth disorders ear disorders (otitis, earache, ear pain)	7/100(7%)	7/100(7%)	3%
Endocrine disorders Hypothyroidism		1/100(1%)	3%
Eye disorders eye disorders (change in vision, conjunctivitis, styes)	8/100(8%)	9/100(9%)	3%
Gastrointestinal disorders abdominal pain or cramping	16/100(16%)	21/100(21%)	3%
bloating or gas	18/100(18%)	5/100(5%)	3%
BORBORYGMI	6/100(6%)	2/100(2%)	3%

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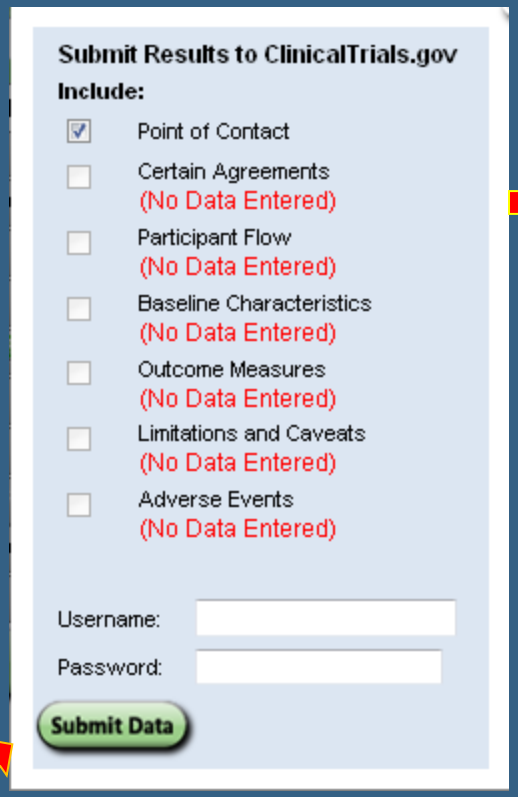
Submitting Data from BTRIS to ClinicalTrials.gov



ClinicalTrials.gov PRS
Protocol Registration and Results System

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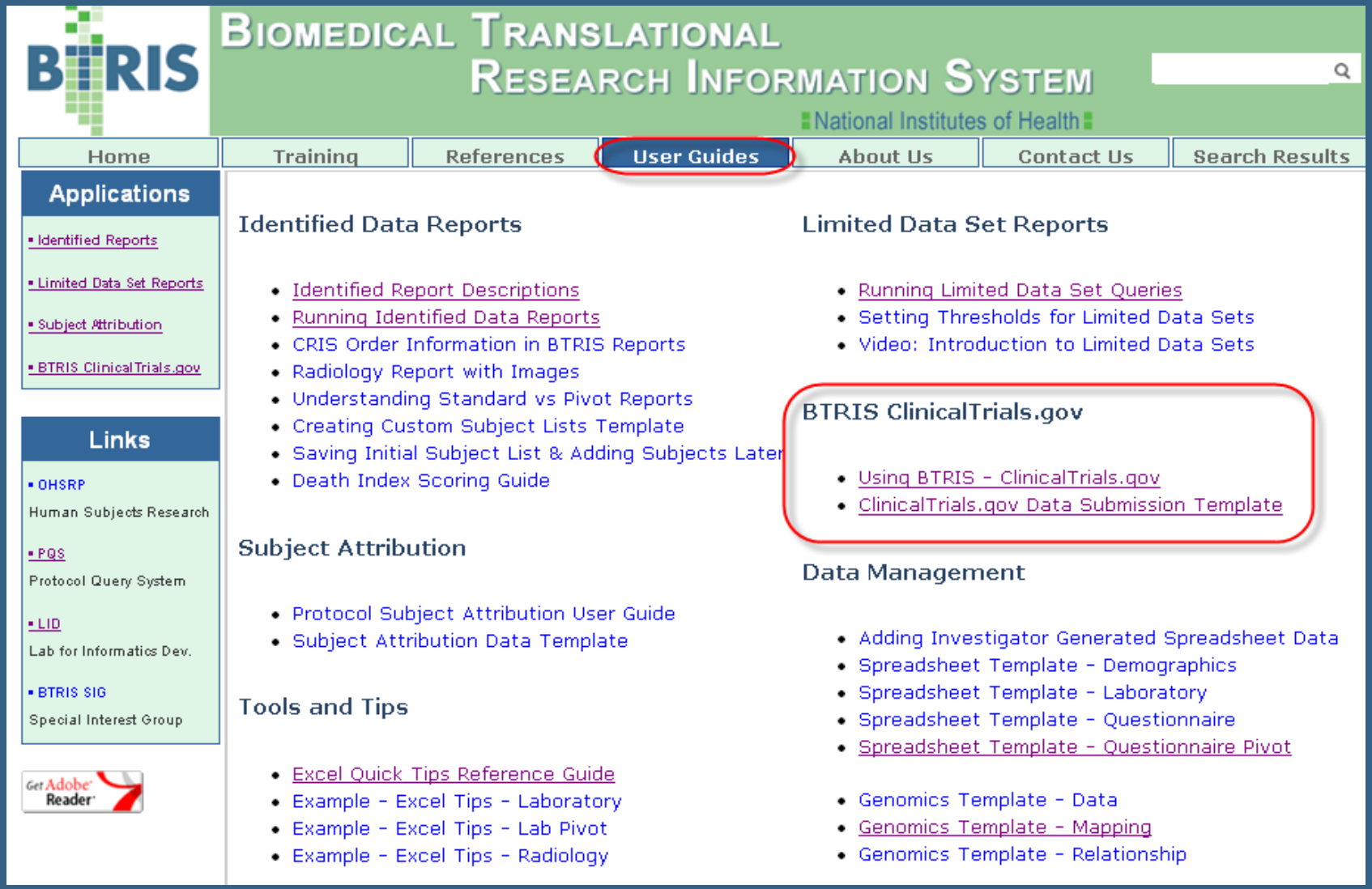
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PQS
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LID
Lab for Informatics Dev.
BTRIS SIG
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Protocol Subject Attribution User Guide
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Example - Excel Tips - Laboratory
Example - Excel Tips - Lab Pivot
Example - Excel Tips - Radiology
Limited Data Set Reports
Running Limited Data Set Queries
Setting Thresholds for Limited Data Sets
Video: Introduction to Limited Data Sets
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Using BTRIS - ClinicalTrials.gov
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Adding Investigator Generated Spreadsheet Data
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Spreadsheet Template - Laboratory
Spreadsheet Template - Questionnaire
Spreadsheet Template - Questionnaire Pivot
Genomics Template - Data
Genomics Template - Mapping
Genomics Template - Relationship

BTRIS Website

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BTRISSupport@nih.gov

301-827-8270